



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,151	01/15/2004	Farzan Filsoufi	MSSM-001	7208
24353	7590	01/26/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/760,151	FILSOUFI, FARZAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul B. Prebilit	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-19 is/are pending in the application.  
4a) Of the above claim(s) 3,4,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/26/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Claims 3, 4, 10, 11, and 20-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 22, 2005.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7-9, 12, and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Streeter (US 2002/065554). Streeter discloses a structure for attachment to a prolapsed leaflet and to extend over one or two leaflets; see Figures 2, 3, 5, 7, and 8-10 as well as the abstract and paragraphs [0005] to [0011]. The Streeter device is capable of being attached to the valve leaflets in that it can be attached to the annulus and extends over one or both leaflets of the heart valve; see Figures 8-10 and also see paragraphs [0028] to [0031]. Clearly sutures could be looped around the structure and extended through the leaflets. For these reasons, the claim language is considered fully met.

Regarding claim 2, the structure of Streeter can be made with metal or wire such that it would be inherently be at least semi-rigid to the extent that this language can be give patentable weight; see paragraph [0025].

With regard to claim 18 and the language "fixation means for affixing", this limitation meets the three-prong test per MPEP 2181 and thereby invokes 35 USC 112, 6<sup>th</sup> paragraph. Streeter's element (sutures or staples) is considered equivalent to Applicant's means for attaching (see claim 19) because it performs the same function in substantially the same way and produces the substantially the same result as the corresponding element of Applicant's specification; see MPEP 2183 that is incorporated herein by reference.

Claims 1, 5, 6, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabbay (US 6,419,695). Gabbay anticipates the claim language where the structure of Gabbay is attachable to an intact valve, is capable of attachment via sutures to a prolapsed leaflet, and has a structure that is capable of coapting with an adjacent leaflet as claimed; see the figures and column 1, line 60 to column 2, line 29.

Regarding claim 6, the bifurcated configuration is that of the buttress that has two branches. The prolapsed leaflet could be attached between the two branches by sutures.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streeter (US 2002/065554) alone. Streeter meets the claim language as explained

in the Section 102 rejection utilizing Streeter, but fails to disclose the particular dimensions as claimed. However, when the only difference between the prior art and the claims is a recitation of some relative dimensions and the prior art device would not perform differently than the claimed device, the claimed device would have been considered *prima facie* obvious to an ordinary artisan. The following is an excerpt from MPEP 2144.04:

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

### ***Response to Arguments***

Applicant's arguments filed November 10, 2005 have been fully considered but they are not persuasive.

Applicant argues that Streeter fails to disclose "a structure that attaches to the prolapsing leaflet"; see page 6 of the response filed November 10, 2005. However, the Examiner asserts that since the Streeter device is capable of attachment to the valve leaflet in that it is attachable to the annulus where it would extend over one or both leaflets of a heart valve in use, it is also capable of being attached to the immediately adjacent leaflets via sutures; see Figures 3 and 8-10 as well as paragraphs [0028] to [0031]. For this reason, the claim language is considered fully met. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the annulus forms the base of the leaflets and is immediately adjacent thereto, it is clear that one could suture the Streeter device to the portion of the leaflet immediately adjacent the annulus.

In response to the traversal of the Gabby rejection (see page 6 of the response), Gabbay's device is inherently for attachment to a prolapsed leaflet because it is for repair thereof and can be attached to the full annulus of a heart valve (i.e. thus, it can be sutured to the leaflets' outer edges). Furthermore, Gabbay's device defines a coapting surface for a prolapsed leaflet; see column 1, lines 28-34 and column 1, line 60 to column 2, line 9. Since Gabbay's device is capable of being used in the manner claimed, it clearly reads on the claim language.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3738

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738